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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,964	02/04/2002	Keith Biggadike	PG4709	6058

7590 06/03/2003

Glaxo Wellcome Inc.
5 Moore Drive, Mai B497
Durham, NC 27709

EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/066,964	BIGGADIKE, KEITH	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

First Office Action on the Merits

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

W 2. Claims 1-19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 18, 22 and 23 of copending Application No. 09/958,050. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-17, 20, 21 and 24-26 of copending Application No. 09/958,050. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone and a hydrofluoroalkane gas. The difference between the two applications is based on the scope of the claimed compositions, i.e., the latter application, unlike the present application, is not limited to compositions comprising a hydrofluoroalkane gas.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 10-18 of U.S. Patent No. 6,537,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone. The difference between the two is based on the scope of the claimed compositions, i.e., the present application, unlike U.S. Patent No. 6,537,983, is limited to compositions comprising 17α-(2-furanylcarbanoyloxy) ester of fluticasone.

6. Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/066,951. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone. The difference between the two applications is based on the scope of the claimed compositions, i.e., the latter application, unlike the present application, encompasses compositions comprising other esters of fluticasone.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 10-18 of copending Application No. 10/066,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone. The difference between the two applications is based on the scope of the claimed compositions, i.e., the latter application, unlike the present application, is limited to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone and a β_2-adrenoreceptor agonist.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

see p. 8 lines 33 - p. 9 line 5

p. 12 line 6-27 of present spec.

or See paragraph 0029 of '836

8. Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/067,020. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone. The difference between the two applications is based on the scope of the claimed compositions, i.e., the latter application, unlike the present application, is limited to a formulation comprising an aqueous suspension of the 17α-(2-furanylcarbanoyloxy) ester of fluticasone.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 10 and 11 of copending Application No. 10/200,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone. The difference between the two applications is based on the scope of the claimed compositions, i.e., the latter application, unlike the present application, is limited to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone in crystalline form.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/241,658. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone. The difference between the two applications is based on the scope of the claimed compositions, i.e., the latter application, unlike the present application, is limited to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone in crystalline form.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

W 11. Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24, 26 and 27 of copending Application No. 10/067,010. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone. The difference between the two applications is based on the scope of the claimed compositions, i.e., the latter application, unlike the present application, is limited to

compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone in crystalline form.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 8-14 of copending Application No. 10/281,735. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α-(2-furanylcarbanoyloxy) ester of fluticasone. The difference between the two applications is based on the scope of the claimed compositions, i.e., the latter application, unlike the present application, encompasses compositions comprising other esters of fluticasone.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Other Matters

13. The closest prior art, Adjei et al. (US patent No. 6,261,539) teach esters of fluticasone such as the furoate (see col. 2, lines 59-60). However, according to the present specification, when compared to fluticasone propionate, 17α-(2-furanylcarbanoyloxy) ester of fluticasone produced greater inhibition of lung eosionphilia and reduction of thymus weight (see page 24, In Vivo Pharmacological Activity).

T lephone Inquiry

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
June 2, 2003